



Patient Information Sheet

Sertraline hydrochloride (marketed as Zoloft)

This is a summary of the most important information about Zoloft. For details, talk to your healthcare professional.

FDA ALERT [05/2005] – Suicidal Thoughts or Actions in Children

Patients with depression or other mental illnesses often think about or attempt suicide. Taking antidepressants may increase suicidal thoughts and actions in about 1 out of 50 people 18 years or younger. Closely watch anyone taking antidepressants, especially early in treatment or when the dose is changed. Patients who become irritable or anxious, or have new or increased thoughts of suicide or other changes in mood or behavior should be evaluated by their healthcare professional right away. FDA has approved Zoloft for use in children only if they have obsessive-compulsive disorder.

This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.

What Is Zoloft?

Zoloft is in a class of medicines called selective serotonin reuptake inhibitors (SSRIs). Zoloft is used to treat:

- Depression
- Obsessive-compulsive disorder (OCD)
- Panic disorder
- Posttraumatic stress disorder (PTSD)
- Premenstrual dysphoric disorder (PMDD)
- Social anxiety disorder (SAD)

Who Should Not Take Zoloft?

- **Never take Zoloft if you are taking another drug used to treat depression, called a Monoamine Oxidase Inhibitor (MAOI), or if you have stopped taking an MAOI in the last 14 days. Taking Zoloft close in time to an MAOI can result in serious, sometimes fatal, reactions, including:**
 - High body temperature
 - Coma
 - Seizures (convulsions)

MAOI drugs include Nardil (phenelzine sulfate), Parnate (tranylcypromine sulfate), Marplan (isocarboxazid), and other brands.

- **Never take Zoloft if you are taking Orap (pimozide), a drug used to treat Tourette's disorder, because it can result in serious heart beat problems.**
- Never take Zoloft oral concentrate if you are taking Antabuse (disulfiram), used to treat alcoholism, because Zoloft oral concentrate contains alcohol.

What Are The Risks?

- **Suicidal thoughts or actions:** See FDA Alert.
- **Stopping Zoloft:** Do not stop taking Zoloft suddenly because you could get side effects. Your healthcare professional will slowly decrease your dose.
- **Bleeding problems:** Zoloft may cause bleeding problems, especially if taken with aspirin, NSAIDs (nonsteroidal anti-inflammatory drugs, such as ibuprofen or naproxen), or other drugs that affect bleeding.
- **Mania:** You may become unusually hyperactive, excitable or elated.
- **Seizures:** You may experience a seizure (convulsion), even if you are not taking Zoloft close in time with a MAOI.
- **Weight loss:** Zoloft can cause weight loss. Children who take it for a long time should have their growth and body weight measured regularly.
- **Pregnancy:** Tell your healthcare professional if you are, or may be, pregnant because babies delivered to mothers taking Zoloft late in pregnancy have developed problems, such as difficulty breathing and feeding.
- **Sexual problems:** You may have problems with impotence (erectile dysfunction), abnormal ejaculation, difficulty reaching orgasm, or decreased libido (sexual desire).
- **Other side effects** include nausea, diarrhea, difficulty sleeping, dry mouth, and sleepiness.
- **Tell your healthcare professional** about all your medical conditions, especially if you have liver or heart disease. Tell your healthcare professional if you are breast-feeding or plan to breast-feed your baby.

Are There Any Interactions With Drugs or Foods?

- Zoloft may interact with medicines other than the ones already mentioned in this information sheet. These interactions can cause serious side effects. Tell your healthcare professional about all medicines, vitamins, and herbal supplements you take, especially those
 - that affect bleeding
 - used to treat anxiety, mental illness, depression, or heart problems
- If you plan to drink alcohol, talk to your healthcare professional.

How Do I Take Zoloft?

- Zoloft is taken by mouth, with or without food, once a day.
- Dilute Zoloft oral concentrate, but **only** in ½ cup of water, ginger ale, lemon/lime soda, lemonade or orange juice. Take immediately after mixing. Tell your doctor if you are allergic to latex because the dropper to measure Zoloft oral concentrate contains natural rubber.

Is There Anything Else I Need to Know?

You can get more information about antidepressants at:

<http://www.fda.gov/cder/drug/antidepressants/default.htm>

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Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570
Druginfo@cder.fda.gov

